K093695

510(k) Summary for PEAK PlasmaBlade® 3.0S

APR 1 8 2010

1. Submitter Name and Address:

PEAK Surgical, Inc.
2464 Embarcadero Way
Palo Alto, CA 94303
Phone: 650-331-3020
Fax: 650-331-3293

Contact: Lois Nakayama

Date prepared: January 18, 2010

2. Device Name:

Trade Name: PEAK PlasmaBlade® 3.0S

Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulation Number: 21 CFR § 878.4400

Product Code: GEI

Regulatory Class: Class II

3. Predicate Devices:

PEAK PlasmaBlade® 4.0 (K082786)

4. Device Description:

The PEAK PlasmaBlade® 3.0S consists of a single insulated bendable blade, telescoping shaft that can be configured in both standard and extended length and a handle with integrated controls and cable. The finger grip also incorporates a suction lumen for the evacuation of smoke and fluids.

The PlasmaBlade 3.0S is an addition to the PEAK PlasmaBlade Family of Tissue Dissection devices which include the PlasmaBlade 4.0, PlasmaBlade Needle, and PlasmaBlade EXT.

5. Intended Use:

The PEAK PlasmaBlade® 3.0S is indicated for cutting and coagulation of soft tissue during General, Plastic and reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

6. Technological Characteristics

The PEAK PlasmaBlade® 3.0S is similar to the predicate device in output energy, delivery system and materials. They are both electrosurgical instruments used to cut and coagulate soft tissue, utilizing RF powered distal ends. The modifications to the electrode, shaft and finger grip do not significantly affect the safety or effectiveness of the device.

7. Performance Data:

Laboratory and performance tests were executed to ensure that the device functioned as intended and met design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.

8. Sterilization

The PEAK PlasmaBlade® 3.0 is provided sterile. The device is not intended for reuse or resterilization.

9. Conclusion:

By virtue of design, technology, principle of operation and intended use, the PEAK PlasmaBlade® 3.0S is substantially equivalent to the predicate device. In establishing substantial equivalence to the predicate device, PEAK Surgical evaluated the indications for use, materials incorporated, product specification and energy requirements of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

PEAK Surgical, Inc.
% Ms. Lois Nakayama
2464 Embarcadero Way
Palo Alto, California 94303

Re: K093695
Trade/Device Name: PEAK PlasmaBlade® 3.0S
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 26, 2010
Received: March 29, 2010

Dear Ms. Nakayama:

This letter corrects our substantially equivalent letter of April 13, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

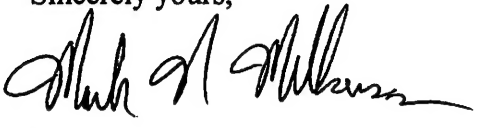
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K093695

Device Name: PEAK PlasmaBlade® 3.0S

Indications for Use:

The PEAK PlasmaBlade® 3.0S Tissue Dissection Device is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093695

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)